

## MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder (PTSD): Eighth Update on Study Progress

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Our preliminary clinical impression is that the supplemental dose extends the period during which the most intense emotional processing occurs.

SINCE MY LAST UPDATE both the Food and Drug Administration (FDA) and our Institutional Review Board (IRB) have given us approval to make two significant protocol changes:

1) To add a supplemental dose of 62.5 mg of MDMA (or placebo) two to two- and-a-half hours after the initial dose of 125 mg. 2) To add a third MDMA-assisted psychotherapy session both for subjects who receive MDMA in the first two experimental sessions and for subjects who initially receive placebo and then go on to participate in the open-label MDMA portion of the protocol.

Thus far three subjects have received the supplemental dose of MDMA or placebo on a total of 6 occasions and one subject has had a third MDMA-assisted “experimental session” in the open label stage. Our preliminary clinical impression is that the supplemental dose is useful. It does not appear to change the intensity of the experience, but it does extend the period during which the most intense emotional processing occurs. There have been no problems associated with the supplemental dose. In one case the blood pressure and pulse did go higher than they had before the supplemental dose, but did not reach dangerous levels or require treatment. It is also our impression that the third MDMA session may provide additional benefit, though we do not yet have formal outcome data following this session.

The overall progress of the study is as follows:

- Fifteen subjects have been enrolled, one has dropped out, twelve have completed the original double blind protocol and two are currently enrolled.

- After receiving placebo in the first stage, four subjects have gone on to the open-label stage (which includes two or three MDMA-assisted psychotherapy sessions along with additional non-drug follow-up psychotherapy sessions). Three have completed this stage and the third recently underwent the third experimental session but has not yet completed the follow-up sessions and final symptom measures.

- We have completed telephone screening on 99 potential subjects.

- One potential new subject has passed formal screening and two others are scheduled to have it.

Recruitment has still been somewhat slow and our recent limited newspaper advertising was not effective in changing that. Nevertheless, we are slowly continuing to recruit people with crime-related PTSD, and anticipate being able to find the remaining five subjects we need within the next six months. However, we would like to recruit some veterans with war-related PTSD of less than five years duration. We are pursuing some possible referral sources at VA hospitals and we

now have permission from the IRB to post an advertisement on websites that serve veterans.

We are currently working on a request to the IRB to conduct long-term follow up of our subjects. We plan to repeat symptom measures as well as a more general questionnaire six months or more after completion of the present protocol. In the case of our earliest subjects the follow-up will occur more than two years from the study sessions. Along with this added protocol request we will seek to clarify the IRB's media policy regarding our study.

Another important event since my last update was a visit from Drs. Rael Strous and Rakefet Rodrigez, two of the Israeli psychiatrists who have permission for and are on the verge of starting a MAPS-sponsored study very similar to ours investigating MDMA-assisted therapy for war- and terrorism-related PTSD. Annie and I really enjoyed the chance to show them our approach to working with subjects and to learn from their insights and ideas. Now, of course, the sad reality is that their work to find better treatments for PTSD is even more urgently needed in Israel and the whole region. •



Illustration: James Montgomery Flagg, Lithograph, 1917. American Treasures of the Library of Congress.